DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

dMD

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10/20/05

[Docket No. 2005D–0362]

Draft Guidance for Industry on Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin Antibodies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies," dated October 2005. The draft guidance document is intended to assist source plasma manufacturers in submitting to FDA the appropriate information when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The draft guidance, when finalized, would supersede the draft reviewers' guide entitled "Disease Associated Antibody Collection Program," dated October 1, 1995.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–

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40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies" dated October 2005. The draft guidance, when finalized, would supersede the draft reviewers' guide, "Disease Associated Antibody Collection Program," dated October 1, 1995. The document provides guidance to source plasma manufacturers in submitting the appropriate information to FDA when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The guidance identifies changes in collection programs that must be documented as minor changes in an annual report to FDA under § 601.12(d) (21 CFR 601.12(d)). These collection programs

include disease-associated IgG antibodies and other existing IgG antibodies. The guidance also identifies labeling changes to be submitted as a supplement for changes being effected under § 601.12(f)(2)(i)(E). The guidance neither includes recommendations related to implementing Immunoglobulin M antibody collection programs, nor does it include recommendations for donors who do not meet all donor suitability requirements under 21 CFR 640.63.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

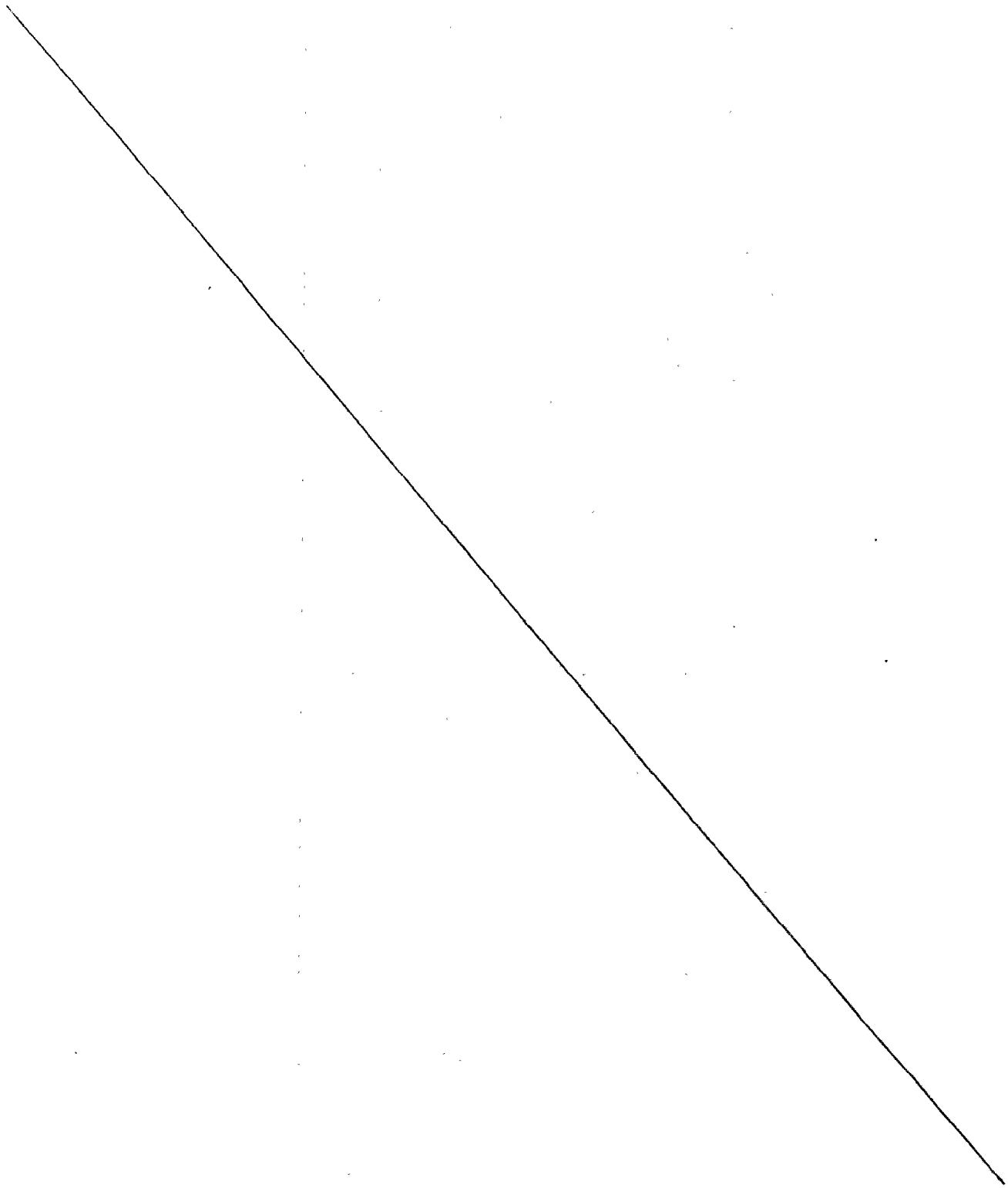
II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in this guidance was approved under OMB control number 0910–0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are

available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 10/12/05
October 12, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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